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| EXAMINER | |
|---|---|
| HORNBERGER, JENNIFER LEA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3734 | |

| NOTIFICATION DATE | DELIVERY MODE |
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| 05/27/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPDOCKET@THOMPSONCOBURN.COM

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/936,587 | LUTHRA ET AL. | |
| | Examiner | Art Unit | |
| | JENNIFER L. HORNBERGER | 3734 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 September 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The amendment to the claims filed on 9/13/2001 does not comply with the requirements of 37 CFR 1.121(c) because claim 1 and its status were not included in the listing of the claims. However, since all claims depend, directly or indirectly from claim 1, it has been examined as originally filed. Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) *Claims*. Amendments to a claim must be made by rewriting the entire claim with all changes (*e.g.*, additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (*e.g.*, Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, *i.e.*, without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, *i.e.*, without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-4, 6-13, 19, 20, 24-32, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al (US 5,683,448) in view of Luthra et al. (WO 97/41164).

Regarding claim 1, Cragg et al. disclose a flexible endoprosthesis comprising an array of consecutive aligned cylindrical stent elements (11) in the form of a plurality of sequentially connected radially stable outwardly biased cylindrical springs constructed of wire wound in zigzag form and a one-piece tubular flexible material (13) maintained in open tubular form by the array of stent elements (Fig. 1). Cragg et al. disclose the tubular flexible material (13) may be coated with a drug substance (col. 3, ln. 41-43), but is silent as to the composition of the drug coating. Luthra et al disclose polymers, used in a drug coating for medical devices, comprising a polymer backbone having pendant groups, obtainable by polymerizing monomers having such groups, characterized in that said polymers are obtained by copolymerizing monomers of at least two different classes selected from: a) monomers having sulphate groups b) monomers having sulphonate groups c) monomers having sulphamate groups d) monomers having polyoxyalkylene ether groups, and e) monomers having zwitterionic groups (see abstract and claim 2).

Therefore, it would have been obvious to one of ordinary skill in the art to have used the polymer drug coating as taught by Luthra et al. in the stent and graft combination of Cragg et al. to provide non-thrombogenic or anti-thrombogenic properties.

Regarding claim 2, Luthra et al. disclose polymers are obtained by copolymerizing monomers of at least two different classes selected from: a) monomers having sulphate groups b) monomers having sulphonate groups c) monomers having sulphamate groups, and d) monomers having polyoxyalkylene ether groups (see claim 1 of Luthra).

Regarding claim 3, Luthra et al. disclose the polymers are obtained by copolymerizing monomers of two only of the respective said different classes.

Regarding claim 4, Luthra et al. disclose the polymer comprises an additional comonomer having pendant heparin, hirudin, warfarin or hyaluronic acid groups (see abstract).

Regarding claim 6, Cragg et al. disclose the stent elements are permanently attached to the array of cylindrical stent elements (col. 2, ln. line 60-67).

Regarding claim 7, Cragg et al. disclose the tubular flexible material (13) is attached by sewing, welding, an adhesive or mechanical clips (col. 3, ln. 19-20)..

Regarding claim 8, Cragg et al. disclose the tubular flexible material is inside the stent elements (col. 3, ln. 25-30).

Regarding claim 9, Cragg et al. disclose the tubular flexible material is outside the stent elements (col. 3, ln. 25-30).

Regarding claim 10, Cragg et al. disclose the stent elements are sandwiched between two flexible tubes (col. 3, ln. 25-30).

Regarding claim 11, Cragg et al. disclose the stent elements are encapsulated by the tubular flexible material (col. 3, ln. 25-30).

Regarding claim 12, Cragg et al. disclose the tubular flexible material (13) is a textile fabric, a woven fabric, or a knitted fabric (col. 3, ln. 31-36).

Regarding claim 13, Cragg et al. disclose the woven or knitted fabric is made from a polyester yarn (col. 3, ln. 36).

Regarding claim 19, Cragg et al. disclose the stent elements are composed of a wire, wound, in zigzag form into a cylindrical shape (col. 2, ln. 41-50).

Regarding claim 20, Cragg et al. disclose the wire has a circular cross section or is a flat tape (col. 2, ln. 54).

Regarding claim 24, Cragg et al. disclose the individual stent elements are made from a continuous length of wire so that they remain connected to each other (col. 2, ln. 41-50).

Regarding claim 25, Cragg et al. disclose the stent elements are made from spring-tempered metal (col. 2, ln. 58).

Regarding claim 26, Cragg et al. disclose the spring-tempered metal is stainless steel (col. 2, ln. 58).

Regarding claim 27, Cragg et al. disclose the stent elements are made from a shape memory alloy (col. 2, ln. 52)

Regarding claim 28, Cragg et al. disclose the shape memory alloy wire is martensitic at temperatures lower then 37°C (col. 4, ln. 5-9).

Regarding claim 29, Cragg et al. disclose the shape memory alloy wire is austenitic at or above a temperature of 37°C (col. 4, ln. 12-15).

Regarding claim 30, Cragg et al. disclose the shape memory alloy wire is in superelastic form at or above a temperature of 37°C (col. 4, ln. 12-15).

Regarding claim 31, Cragg et al. disclose the stent elements are made from a malleable material (col. 2, ln. 58).

Regarding claim 32, Cragg et al. disclose the malleable material is malleable stainless steel (col. 2, ln. 58).

Regarding claim 34, Cragg et al. disclose the individual stent elements are arranged so as to be alternately of opposite phase with the apexes of the zigs in one stent element in contact with the next, so as to give maximum stability to the device during delivery (Fig. 1).

3. Claims 1, 14-18, 21, 22, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vonesh et al. (US 6,336,937) in view of Luthra et al. (WO 97/41164).

Regarding claim 1, Vonesh et al. disclose a flexible endoprosthesis comprising an array of consecutive aligned cylindrical stent elements (20) in the form of a plurality of sequentially connected radially stable outwardly biased cylindrical springs constructed of wire wound in zigzag form and a one-piece tubular flexible material (26) maintained in open tubular form by the array of stent elements (Fig. 1). Luthra et al disclose polymers, used in a drug coating for medical devices, comprising a polymer backbone having pendant groups, obtainable by polymerizing monomers having such groups, characterized in that said polymers are obtained by copolymerizing monomers of at least two different classes selected from: a) monomers having sulphate groups b) monomers having sulphonate groups c) monomers having sulphamate groups d) monomers having polyoxyalkylene ether groups, and e) monomers having zwitterionic groups (see abstract and claim 2). Therefore, it would have been obvious to one of ordinary skill in the art to

have used the polymer drug coating as taught by Luthra et al. in the stent graft combination of Vonesh et al. to provide non-thrombogenic or anti-thrombogenic properties.

Regarding claim 14, Vonesh et al. disclose the tubular flexible material is a continuous tubular element or film (col. 9, ln. 17-33)

Regarding claim 15, Vonesh et al. disclose the continuous tubular element or film is formed from a synthetic polymer (col. 9, ln. 17-33).

Regarding claim 16, Vonesh et al. disclose the synthetic polymer is a polyester, or a polyurethane (col. 9, ln. 17-33).

Regarding claim 17, Vonesh et al. disclose the continuous tubular element or film is formed from an elastomer (col. 9, ln. 17-33).

Regarding claim 18, Vonesh et al. disclose the elastomer is silicone rubber or polytetrafluoroethylene (col. 9, ln. 17-33).

Regarding claim 21, Vonesh et al. disclose the stent elements are constructed from a metallic or polymeric tube by laser cutting or chemical etching (col, 18, ln. 65).

Regarding claim 22, the wire of each stent element has both ends connected to each other so as to have a continuous form (Fig. 17).

Regarding claim 33, Vonesh et al. disclose the individual stent elements are arranged so as not to touch each other or to interfere with each other so as to give maximum flexibility to the complete device during delivery and subsequent operation (Fig 17).

4. Claims 1 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al (US 2001/0000188) in view of Luthra et al. (WO 97/41164).

Regarding claim 1, Lenker et al. disclose a flexible endoprosthesis comprising an array of consecutive aligned cylindrical stent elements (14) in the form of a plurality of sequentially connected radially stable outwardly biased cylindrical springs constructed of wire wound in zigzag form and a one-piece tubular flexible material (18) maintained in open tubular form by the array of stent elements (Fig. 11). Luthra et al disclose polymers, used in a drug coating for medical devices, comprising a polymer backbone having pendant groups, obtainable by polymerizing monomers having such groups, characterized in that said polymers are obtained by copolymerizing monomers of at least two different classes selected from: a) monomers having sulphate groups b) monomers having sulphonate groups c) monomers having sulphamate groups d) monomers having polyoxyalkylene ether groups, and e) monomers having zwitterionic groups (see abstract and claim 2). Therefore, it would have been obvious to one of ordinary skill in the art to have used the polymer drug coating as taught by Luthra et al. in the stent graft combination of Lenker et al. to provide non-thrombogenic or anti-thrombogenic properties.

Regarding claim 5, Lenker et al. disclose the polymer encapsulates the array of stent elements and the tubular flexible material is a hydrogel (paragraph 72).

5. Claims 1, 19, 23, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottenceau et al. (US 5,897,589) in view of Luthra et al. (WO 97/41164).

Regarding claim 1, Cottenceau et al. disclose a flexible endoprosthesis comprising an array of consecutive aligned cylindrical stent elements (1) in the form of a plurality of sequentially connected radially stable outwardly biased cylindrical springs constructed of wire wound in zigzag form and a one-piece tubular flexible material (54) maintained in open tubular form by the array of stent elements (Fig. 1). Luthra et al

disclose polymers, used in a drug coating for medical devices, comprising a polymer backbone having pendant groups, obtainable by polymerizing monomers having such groups, characterized in that said polymers are obtained by copolymerizing monomers of at least two different classes selected from: a) monomers having sulphate groups b) monomers having sulphonate groups c) monomers having sulphamate groups d) monomers having polyoxyalkylene ether groups, and e) monomers having zwitterionic groups (see abstract and claim 2). Therefore, it would have been obvious to one of ordinary skill in the art to have used the polymer drug coating as taught by Luthra et al. in the stent graft of Cottenceau et al. to provide non-thrombogenic or anti-thrombogenic properties.

Regarding claim 19, Cottenceau et al. disclose the stent elements are composed of wire, wound, in zigzag form into a cylindrical shape (Fig. 8).

Regarding claim 23, Cottenceau et al. disclose the ends of the wire of each stent element are joined by overlapping and binding with suture material (57; Figures 8 and 10).

Regarding claim 35, the connections between individual stent elements are bound together to form a longitudinal spine in the complete device (Fig. 7)

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. L. H./
Examiner, Art Unit 3734

jlh
4/24/08

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731